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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,107	10/16/2001	Andrew C. Hiatt	EPI3002E	6455

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EXAMINER
COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,107	HIATT ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 86 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 86 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 86 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 86 is indefinite in the recitation of "encoding IgG immunoglobulins that are devoid of sialic acid residues and galactose". It is unclear how nucleotide sequences would encode the absence of sialic acid residues and galactose, as nucleotide sequences are ordinarily interpreted as encoding information pertaining only to the amino acid sequences of polypeptides, as opposed to encoding information pertaining to both the amino acid sequences of polypeptides and the absence of sialic acid residues and galactose.

Claim 86 is also indefinite in that it is unclear whether the tobacco plant comprises nucleotide sequences and galactose, or whether the tobacco plant comprises nucleotide sequences.

Claim 86 is additionally indefinite in that it is unclear whether "that", as recited in "that are devoid of sialic acid residues and galactose", refers to "immunoglobulins" or to "nucleotide sequences".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 86 is rejected under 35 U.S.C. 102(b) as being anticipated by Hiatt et al. (Nature, Vol. 342, 2 November 1989, pages 76-78).

The claim is drawn to a transgenic tobacco plant that comprises nucleotide sequences encoding IgG immunoglobulins that are devoid of sialic acid residues and galactose.

Hiatt et al. teach a transgenic tobacco plant that comprises nucleotide sequences encoding a 6D4 IgG_1 immunoglobulin (page 77 Table 1). Although Hiatt et al. do not explicitly teach that their transgenic plants comprise immunoglobulins that are devoid of sialic acid residues and galactose, the transgenic plants taught by Hiatt et al. would necessarily comprise immunoglobulins that are devoid of sialic acid residues and galactose, as the claim only requires that the transgenic plant comprise immunoglobulin coding nucleotide sequences.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 86 is rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,303,341, issued October 16, 2001.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claim 86 is directed to a transgenic tobacco plant that comprises nucleotide sequences encoding IgG immunoglobulins that are devoid of sialic acid residues and galactose, whereas claims 1-53 of U.S. Patent No. 6,417,429 are directed to immunoglobulins, including IgG immunoglobulins, produced in transgenic plant cells, including tobacco cells, as well as immunoglobulin compositions and methods of making immunoglobulins in plant cells. Although

U.S. Patent No. 6,303,341 does not explicitly teach transgenic plants comprising immunoglobulins that are devoid of sialic acid residues and galactose, the transgenic plants taught by U.S. Patent No. 6,303,341 would necessarily comprise immunoglobulins that are devoid of sialic acid residues and galactose, as claim 86 only requires that the transgenic plant comprise immunoglobulin coding nucleotide sequences.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 86 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-69 of U.S. Patent No. 6,417,429. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 86 is directed to a transgenic tobacco plant that comprises nucleotide sequences encoding IgG immunoglobulins that are devoid of sialic acid residues and galactose, whereas claims 1-69 of U.S. Patent No. 6,417,429 are directed to transgenic plants, including tobacco plants, comprising plant cells containing nucleotide sequences encoding immunoglobulin heavy and

light chain polypeptides, including IgG immunoglobulin heavy and light chain polypeptides. U.S. Patent No. 6,417,429 also indicates that the immunoglobulins produced in plant cells are devoid of sialic acid residues and galactose (column 59 line 55 through column 60 line 58).

Claim 86 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Patent No. 6,303,341. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 86 is directed to a transgenic tobacco plant that comprises nucleotide sequences encoding IgG immunoglobulins that are devoid of sialic acid residues and galactose, whereas claims 1-53 of U.S. Patent No. 6,417,429 are directed to immunoglobulins, including IgG immunoglobulins, produced in transgenic plant cells, including tobacco cells, as well as immunoglobulin compositions and methods of making immunoglobulins in plant cells. Although U.S. Patent No. 6,303,341 does not explicitly teach transgenic plants comprising immunoglobulins that are devoid of sialic acid residues and galactose, the transgenic plants taught by U.S. Patent No. 6,303,341 would necessarily comprise immunoglobulins that are devoid of sialic acid residues and galactose, as claim 86 of the instant application only requires that the transgenic plant comprise immunoglobulin coding nucleotide sequences.

Claim 86 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,639,947. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 86 is directed to a transgenic tobacco plant that comprises nucleotide sequences encoding

IgG immunoglobulins that are devoid of sialic acid residues and galactose, whereas claims 1-11 of U.S. Patent No. 5,639,947 are directed to transgenic plants, including tobacco plants, comprising plant cells containing nucleotide sequences encoding immunoglobulin heavy and light chain polypeptides, and methods of making transgenic plants. The transgenic plants exemplified in U.S. Patent No. 5,639,947 include transgenic plants comprising nucleotide sequences encoding an IgG immunoglobulin. Although U.S. Patent No. 5,639,947 does not explicitly teach transgenic plants comprising immunoglobulins that are devoid of sialic acid residues and galactose, the transgenic plants taught by U.S. Patent No. 5,639,947 would necessarily comprise immunoglobulins that are devoid of sialic acid residues and galactose, as claim 86 of the instant application only requires that the transgenic plant comprise immunoglobulin coding nucleotide sequences.

Claim 86 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,202,442. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 86 is directed to a transgenic tobacco plant that comprises nucleotide sequences encoding IgG immunoglobulins that are devoid of sialic acid residues and galactose, whereas claims 1-5 of U.S. Patent No. 5,202,442 are directed to glycopolypeptide multimer/plant material compositions and glycopolypeptide multimers produced in transgenic plants. The transgenic plants exemplified in U.S. Patent No. 5,202,442 include transgenic plants comprising nucleotide sequences encoding an IgG immunoglobulin glycopolypeptide multimer. Although U.S. Patent No. 5,202,442 does not explicitly teach transgenic plants comprising immunoglobulins that are

devoid of sialic acid residues and galactose, the transgenic plants taught by U.S. Patent No. 5,202,442 would necessarily comprise immunoglobulins that are devoid of sialic acid residues and galactose, as claim 86 of the instant application only requires that the transgenic plant comprise immunoglobulin coding nucleotide sequences.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

September 24, 2003

PHUONG T. BUI
PRIMARY EXAMINER